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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/524,819 | 02/18/2005 | Ulrich Kautz | 26588U | 1996 |
| 34375 | 7590 | 11/09/2005 | EXAMINER | |
| NATH & ASSOCIATES PLLC 1030 FIFTEENTH STREET, N.W. SIXTH FLOOR WASHINGTON, DC 20005 | | | AULAKH, CHARANJIT | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |

DATE MAILED: 11/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/524,819

Applicant(s)

KAUTZ ET AL.

Examiner

Charanjit S. Aulakh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 18-20 is/are rejected.
- 7) ☒ Claim(s) 6-13 and 15 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1 page.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. According to a preliminary amendment filed on Feb. 18, 2005, the applicants have canceled claims 14, 16 and 17; amended claims 1-13, 15, 18 and 19 and furthermore, have added new claim 20.
2. Claims 1-13, 15 and 18-20 are now pending in the application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following eight different factors (see *Ex parte Foreman*, 230 USPQ at 547; *Wands*, *In re*, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least four of the above mentioned eight different factors such as quantity of experimentation

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necessary, the amount of direction or guidance provided, presence of working examples, the state of the prior art and the breadth of claims.

The instant compounds are inhibitors of PDE4 activity as shown by in vitro data on pages 61-62. Based on these teachings, the instant compounds will have utility in treating only those specific disease conditions where either PDE4 inhibitors are well known in the prior art to have therapeutic utility or have been shown to have efficacy in known animal models of specific disease conditions. The specification generally mentions hundreds of different disease conditions on pages 55-56 which can be treated by the PDE4 inhibitors. However, there is no teaching either in the specification or prior art references provided showing well established utility of PDE4 inhibitors in all of these disease conditions. There are no working examples present showing efficacy of instant compounds in known animal models of every known airway disorder, dermatoses or any specific illness to be treated by the instant compounds. There is no direction or guidance provided how the instant compounds having PDE4 inhibitory activity in a vitro assay will have utility in treating every known airway disorder, dermatoses or yet unknown illness where PDE4 inhibitors may prove to have therapeutic benefit. The instant compounds of formula (I) encompasses several hundreds of thousands of compounds based on the values of variables R1-R7 and R31 and therefore, in absence of such teachings, guidance and presence of working examples, it would require undue experimentation to demonstrate the efficacy of instant compounds in known animal models of every known airway disorder, dermatoses and yet unknown illness where

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PDE4 inhibitors may prove to have therapeutic benefit and hence their utility in treating these disease conditions.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-5 and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-5, the values of variables R1, R2, R4, R6 and R7 defined as -----completely or predominantly fluorine substituted ----- is vague, confusing and indefinite. What is the need for this term? Does it mean that these groups can not be substituted with a single fluorine group?

In claim 2, the value of variable R5 defined as ---1-4C-alkyl2--- is indefinite since its meaning is not clear and furthermore, lacks antecedent basis.

In claim 2, the value of variable R6 defined as ---1-4C-alkoxy--- is mentioned twice.

Should it be 1-4C alkyl at first occurrence to be consistent with claim 1?

In claim 18, the specific illness treatable by PDE inhibitor are not defined.

In claim 19, specific airway disorders are not defined.

In claim 20, specific skin diseases are not defined.

Allowable Subject Matter

7. Claims 6-13 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

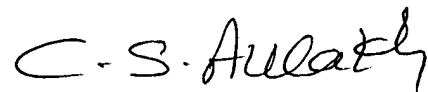
The instant compounds are allowable over the prior art since they are neither disclosed nor obvious over the prior art. In the prior art, Gutterer (WO 02/05616, cited on applicants form 1449) discloses novel 6-phenyl phenanthridines of formula I (see page 1) which are closely related to the instant compounds. However, the compounds of Gutterer differ from the instant compounds in having a hydrogen or an alkyl group (variables R4 and R5) instead of hydroxyl, alkoxy or an ester group at 2nd position of the phenanthridine ring.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charanjit S. Aulakh
Primary Examiner
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